IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 04-1511 CW

TENTATIVE ORDER
CERTIFYING ISSUES AND
GRANTING LEAVE TO SEEK
INTERLOCUTORY APPEAL

IN RE ABBOTT LABORATORIES NORVIR ANTI-TRUST LITIGATION

Defendant Abbott Laboratories manufactures ritonavir, which it sells as Norvir, a protease inhibitor (PI) used to combat HIV infection. When used in small quantities with another PI, Norvir increases the efficacy of that PI. Norvir is unique among PIs in this respect, and is widely prescribed for use as a "booster."

Abbott also manufactures Kaletra, a single pill that contains the PI lopinavir as well as ritonavir (Norvir), which is used to boost the effects of lopinavir. Although effective and widely used, Kaletra causes some patients to experience significant side effects. In 2003, two new PIs were introduced to the market. These PIs were as effective as Kaletra, and were more convenient. Following their release, Kaletra's market share fell.

On December 3, 2003, Abbott raised the wholesale price of Norvir by 400 percent (representing a \$6.84 increase per 100-mg daily dose) while keeping the price of Kaletra constant.

Plaintiffs contend that the price increase in the "booster market," which consists solely of Norvir, was an illegal effort to create or maintain a monopoly for Kaletra in the "boosted market," which Plaintiffs define as the market for those PIs that are prescribed for use with Norvir as a booster.

Plaintiffs sued for monopolization and attempted monopolization in violation of § 2 of the Sherman Act. They have proceeded under the monopoly leveraging theory described in <a href="Image">Image</a> <a href="Image">Technical Services</a>, Inc. v. <a href="Eastman Kodak Co.">Eastman Kodak Co.</a>, 125 F.3d 1195 (9th Cir. 1997). Under this theory, "a monopolist who acquires a dominant position in one market through patents and copyrights may violate § 2 if the monopolist exploits that dominant position to enhance a monopoly in another market." <a href="Id.">Id.</a> at 1216. Plaintiffs also sued for violation of the California Unfair Competition Law and for unjust enrichment.

During the course of this litigation, the Court has issued a number of orders ruling on the various legal issues relating to Plaintiffs' claims. After more than four years of litigation, the parties wish to avoid trial and have reached a negotiated agreement. The Court's legal rulings are now the only real contested issues remaining. Under the agreement, regardless of the outcome of the appeal, Abbott will pay \$10 million, seventy percent of which will be deposited into a cy pres fund and distributed to non-profit organizations that benefit individuals with HIV/AIDS. The remaining thirty percent will be allocated to indirect

purchaser class members who purchased Norvir in California and file valid claims. The agreement will go into effect if this Court certifies an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and the Ninth Circuit allows Abbott to take such an appeal with respect to at least two out of three specific issues discussed in the Court's orders dated October 21, 2004, September 12, 2005, 1 July 6, 2006 and May 16, 2008, 2 each of which denied a dispositive motion by Abbott. If Abbott prevails on appeal, the \$10 million will not be returned and no trial will be held. If Abbott fails to prevail on appeal, it will not proceed to trial, but will pay an additional \$17.5 million to the cy pres fund.

Specifically, Abbott wishes to contest the following rulings of the Court:

1) That, even though Abbott possesses a patent for Norvir, under <u>Blue Shield of Virginia v. McCready</u>, 457 U.S. 465 (1982), Plaintiffs are not precluded as a matter of law from establishing an antitrust injury by virtue of their paying a "penalty" in the form of an increased price for Norvir in the leveraging market if they choose to use a boosted PI that competes with Kaletra, where Plaintiff contends the price increase was designed to create or maintain a monopoly in the leveraged market[; or, in

 $<sup>^{1}</sup>$ The parties' submissions refer to an order dated March 2, 2005, but there is no such order.

 $<sup>^2</sup>$ The order of May 16, 2008 denying Abbott's motion for summary judgment incorporated by reference the Court's order denying Abbott's motions to dismiss in the related cases, Nos. 07-5985, 07-6010, 07-6118, 07-5470, 07-5702 and 07-6120.

the alternative, that Plaintiffs are not precluded as a matter of law from establishing an antitrust injury in the form of a barrier to entry that hinders the introduction of new PIs by Abbott's competitors, even though there is no direct evidence that new drugs to compete with Kaletra have actually been excluded].

- 2) That Plaintiffs are not precluded as a matter of law from establishing at trial that Abbott possesses monopoly power over the market for PIs that are boosted by Norvir by showing that Abbott successfully used exclusionary pricing to slow a market share decline, even though some existing competitors have increased both their market share and their prices since the Norvir price increase[; or, in the alternative, that Plaintiffs are not precluded as a matter of law from establishing at trial that Abbott possesses monopoly power by showing that Abbott owns a dominant share of the market for boosted PIs and that there are significant barriers to entry in the market, notwithstanding Abbott's evidence that it has less than a sixty-five percent share of the market].
- on Abbott's unilateral pricing conduct, Plaintiffs are not required to show that the imputed price of Kaletra is below Abbott's average variable cost of producing it, notwithstanding the Ninth Circuit's decision in <a href="Cascade">Cascade</a>
  <a href="Health Solutions v. PeaceHealth">Health Solutions v. PeaceHealth</a>, 515 F.3d 883 (9th Cir. 2008), which held that, in an antitrust action based on a

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theory of exclusionary bundled discounting, the plaintiffs must ordinarily demonstrate that the imputed price of the competitive product in the bundle is below the average variable cost of producing it.

A district court may certify appeal of interlocutory orders only if three factors are present. First, the issue to be certified must involve a "controlling question of law." 28 U.S.C. § 1292(b). Second, there must be "substantial ground for difference of opinion" on the issue. Id. Third, it must be likely that an interlocutory appeal will "materially advance the ultimate termination of the litigation." Id.

The orders from which Abbott seeks an interlocutory appeal involve controlling questions of law, in that each of the three issues identified above, if decided in its favor, is casedispositive. In addition, considering the novelty of the legal theories presented in this case and the lack of precedent directly on point, there is substantial ground for difference of opinion as to the proper resolution of the issues on appeal. An immediate appeal would also materially advance the ultimate termination of the litigation, in that it would trigger the agreement between the parties, thereby obviating the need for trial, regardless of the outcome of the appeal, and eliminating the possibility of another appeal at a later date. Moreover, the resolution on appeal of any of the above issues in Abbott's favor would also be likely materially to advance the ultimate termination of the related antitrust cases brought against Abbott by direct purchasers and by one of its competitors. Those cases are still in the early stages of litigation.

For these reasons, the Court will permit Abbott to apply	tc
the Ninth Circuit for an interlocutory appeal of the orders	
specified above, and recommends that the appeal be permitted.	